IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

G.D. SEARLE LLC and PFIZER ASIA PACIFIC PTE. LTD.

Plaintiffs,

v.

LUPIN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., MYLAN PHARMACEUTICALS INC., WATSON LABORATORIES, INC., APOTEX INC., and APOTEX CORP.,

Defendants.

Civil Action No. 2:13cv121

COMPLAINT

G.D. Searle LLC and Pfizer Asia Pacific Pte. Ltd. (collectively "Pfizer"), by their attorneys, for their complaint against Lupin Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Mylan Pharmaceuticals Inc., Watson Laboratories, Inc., Apotex Inc., and Apotex Corp. (collectively "Defendants"), allege as follows:

NATURE OF THE ACTION

1. Pfizer has all right, title and interest in United States Reissue Patent No. RE 44,048 (the "'048 patent"), and the right to sue for infringement thereof. This is an action by Pfizer against Defendants for patent infringement of the '048 patent arising from Defendants' filing of Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") which seek approvals to market generic versions of Pfizer's Celebrex® drug product to treat one or more disorders, such as rheumatoid arthritis and osteoarthritis, prior to expiration of the '048 patent and any related period of exclusivity.

2. Pfizer filed this suit on the day the Patent Office issued the '048 patent. On information and belief, Defendants intend to market generic versions of Pfizer's Celebrex® drug product beginning on or about May 30, 2014, which is prior to the expiration of the '048 patent. This will cause Pfizer to suffer irreparable harm—inflicting incalculable damage by causing Pfizer to lose substantial market share, to experience massive price erosion, and to lose goodwill and customers. This irreparable harm to Pfizer will occur even if generic versions of Celebrex® are subsequently removed from the market due to a later judicial determination that the '048 patent is valid, enforceable, and infringed. Accordingly, in the event that Pfizer is unable to obtain a full adjudication on the merits prior to May 30, 2014, it will need to seek a preliminary injunction to prevent such irreparable and irreversible harm.

THE PARTIES

Plaintiffs

3. Plaintiff G.D. Searle LLC ("Searle") is a limited liability company organized under the laws of the State of Delaware, and owns and licenses the '048 patent. G.D. Searle LLC is a wholly owned subsidiary of Pfizer Inc., a corporation organized under the laws of the State of Delaware and having its principal place of business located at 235 East 42nd Street, New York, New York. Pfizer Inc. invests extensively in designing, developing, and evaluating new and innovative pharmaceutical products and sells pharmaceutical products to the public throughout the United States.

4. Plaintiff Pfizer Asia Pacific Pte. Ltd. ("PAPPL") is a private limited company organized and existing under the laws of Singapore, with a principal place of business located at 31 Tuas South Avenue 6, Singapore 637578. PAPPL is the holder of certain rights under the '048 patent, including an exclusive license to manufacture and sell Celebrex®. Pfizer Inc. is the ultimate parent of PAPPL.

Defendants

5. On information and belief, Lupin Pharmaceuticals, Inc., also known as Lupin Pharmaceuticals, USA, Inc. and Lupin Pharmaceuticals, Inc., USA, ("Lupin"), is a corporation organized under the laws of the Commonwealth of Virginia and has its principal place of business at 111 South Calvert Street, Baltimore, Maryland 21202.

6. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized under the laws of the State of Delaware and has its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

7. On information and belief, Mylan Pharmaceuticals Inc. ("Mylan") is a corporation organized under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

8. On information and belief, Watson Laboratories, Inc. ("Watson") is a corporation organized under the laws of the State of Nevada and has its principal place of business at 311 Bonnie Circle, Corona, California 92880.

9. On information and belief, Apotex Inc. is a Canadian corporation and has its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada.

10. On information and belief, Apotex Corp. is a corporation organized under the laws of the State of Delaware and has its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

Lupin

13. Lupin is subject to personal jurisdiction in the Eastern District of Virginia due, among other things, to Lupin's systematic, purposeful, and continuous contacts in this district and its registration to do business in the Commonwealth of Virginia. Furthermore, Lupin is a corporation organized under the laws of the Commonwealth of Virginia, and has a registered agent for service of process in this judicial district.

14. Lupin makes and sells pharmaceutical products, which it distributes in the Eastern District of Virginia and throughout the United States, and for many years has had, and continues to have, substantial sales in this district. Lupin is the fifth largest and fastest-growing generic pharmaceutical company in the United States in terms of prescriptions, and had approximately $363 million in U.S. sales revenue in fiscal year 2012. Lupin has multiple authorized distributors in this judicial district.

15. Lupin has previously availed itself of the benefits of this jurisdiction by filing suit in this Court. *See, e.g.*, *Lupin Limited and Lupin Pharmaceuticals, Inc. v. Sanofi-Aventis Deutschland GMBH et al.*, 2:08-cv-258 (E.D. Va. 2008); *Lupin Limited v. Abbott Laboratories et al.*, 3:06-cv-400 (E.D. Va. 2006) (Lupin Pharmaceuticals as a counterdefendant).

Teva

16. Teva is subject to personal jurisdiction in the Eastern District of Virginia due, among other things, to Teva's systematic, purposeful, and continuous contacts in this district.

17. Teva makes and sells pharmaceutical products, which it distributes in the Eastern District of Virginia, and for many years has had, and continues to have, substantial sales in this district. Teva is the largest generic pharmaceutical company in the United States. One in six of

the 2.6 billion generic prescriptions written in the United States is filled with a Teva product, giving Teva approximately 17% of the total U.S. generic market. Over 1.5 million Teva prescriptions are written each day in the United States, amounting to 1,052 Teva prescriptions per minute. Teva's generic medications are available in most pharmacies across the United States, and, in 2011, 43% of Teva's generic sales in the United States were made directly to drug store chains.

18. Teva has maintained an active license with the Virginia Department of Health Professions as a "Non-Resident Wholesale Distributor" since at least 2007. The Virginia Board of Pharmacy, a Health Regulatory Board for the Virginia Department of Health Professions, mandates that it is unlawful for any corporation, resident or nonresident, to engage in the wholesale distribution of prescription drugs in Virginia without a valid license from the Virginia Board of Pharmacy. A "Non-Resident Wholesale Distributor" license permits the licensed company, located in another state, to directly distribute prescription drugs to pharmacies, physicians, and other "retail" entities throughout the Commonwealth of Virginia. On information and belief, pursuant to its Non-Resident Wholesale Distributor license, Teva distributes prescription drugs in Virginia.

19. In applying to become a "Non-Resident Wholesale Distributor," each applicant must designate a registered agent in Virginia for service of any notice or other legal document. Failure to designate an agent results in designation of the Secretary of the Commonwealth as the applicant's agent. For at least this reason, Teva has consented to service of process in the Commonwealth of Virginia. Furthermore, Teva, through its subsidiary, Barr Laboratories, Inc., is registered to do business in the Commonwealth of Virginia and has a registered agent for service of process in this judicial district.

20. Teva generates billions of dollars in revenues from U.S. sales annually, including many millions of dollars in revenue from sales in the Commonwealth of Virginia, and has done so for many years.

21. Teva's extensive operations include more than 8,000 employees in close to 30 facilities across North America, including facilities in the Commonwealth of Virginia comprising 408,000 square feet used for warehousing, manufacturing, packaging and distribution of Teva's generic products. Teva-authorized distributors selling Teva generic products in this judicial district include, among others, Wal-Mart, Walgreens, CVS, and Rite Aid.

22. Teva is a pharmaceutical vendor for the Minnesota Multistate Contracting Alliance for Pharmacy ("MMCAP"), a Group Purchasing Organization comprised of 46 states, including Virginia, which sells pharmaceuticals to government healthcare facilities in the member states and generates over a billion dollars in sales each year.

23. Teva solicits customers in Virginia using its extensive website. Through Teva's interactive website, customers and potential customers throughout the United States, including in this judicial district, can, among other things: (a) sign up to receive alerts when Teva generic products become available; (b) download Teva's product catalogue, which includes a toll-free phone number to call for order information; (c) download prescribing information for Teva's full product line; (d) submit product return requests; and (e) get advice on how to buy Teva products locally.

24. Teva has previously availed itself of the benefits of this jurisdiction by filing suit in this Court. *See, e.g.*, *Teva Pharmaceuticals v. Glaxosmithkline PLC, et al.*, 2:01-cv-677 (E.D. Va. 2001); *Teva Pharmaceuticals v. Adipex.com, LLC, et al.*, 3:00-cv-43 (E.D. Va. 2000).

Mylan

25. Mylan is subject to personal jurisdiction in the Eastern District of Virginia due, among other things, to Mylan's systematic, purposeful, and continuous contacts in this district and its registration to do business in this district.

26. Mylan is a wholly-owned subsidiary of Mylan Inc., which holds the number two ranking in the United States generics prescription market in terms of both revenue and prescriptions dispensed. Mylan Inc.'s sales in the U.S. are derived principally through Mylan, which is Mylan Inc.'s primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary. One of every eleven prescriptions dispensed in the U.S. is a Mylan Inc. product. Mylan makes and sells pharmaceutical products which it distributes in the Eastern District of Virginia and throughout the United States and for many years has had, and continues to have, substantial sales in this district.

27. Mylan generates billions of dollars in revenues from U.S. sales annually, including many millions of dollars in revenue from sales in the Commonwealth of Virginia. Mylan markets products directly to wholesalers, distributors, retail pharmacy chains, long-term care pharmacies, mail order pharmacies and group purchasing organizations throughout the United States.

28. In 2011, sales to Cardinal Health, Inc. and McKesson Corporation—both nationwide distributors having facilities in the Commonwealth of Virginia—accounted for 13% and 11%, respectively, of Mylan Inc.'s consolidated net revenues. On information and belief, Mylan also sells Mylan Inc.'s generic pharmaceutical products to retail pharmacies having locations in this judicial district, including Wal-Mart, CVS, and Rite-Aid.

29. Mylan has maintained an active license with the Virginia Department of Health Professions as a "Non-Resident Wholesale Distributor" since at least 1999. On information and

belief, pursuant to its Non-Resident Wholesale Distributor license, Mylan distributes prescription drugs in Virginia.

30. Mylan is a pharmaceutical vendor for the MMCAP which sells pharmaceuticals in 46 states, including Virginia.

31. Mylan solicits customers in Virginia using its extensive website. Through Mylan's interactive website, customers and potential customers throughout the U.S., including in this judicial district, can, among other things: (a) submit comments; (b) download Mylan's "Consumer Product Guide," which provides a full listing of all Mylan products; and (c) download medication guides including an "NSAID Patient Medication Guide."

32. Mylan is registered to do business in the Commonwealth of Virginia and has a registered agent for service of process in this judicial district.

33. Mylan has previously availed itself of the benefits of this jurisdiction by filing suit in this Court. *See, e.g., Mylan Pharmaceuticals Inc v. Eli Lilly and Co.*, 3:08-cv-144 (E.D. Va. 2008).

Watson

34. Watson is subject to personal jurisdiction in the Eastern District of Virginia due, among other things, to Watson's systematic, purposeful, and continuous contacts in this district.

35. Watson's parent company, Actavis, Inc. (f/k/a Watson Pharmaceuticals, Inc.) ("Actavis"), derives the vast majority of its revenue from sales of generic pharmaceuticals in the United States, with approximately 84% of total generic net revenue coming from the Company's business in this market. Actavis holds approximately a 10% share of the U.S. generics market. Additionally, Actavis currently markets approximately 40 brand products in the U.S. Actavis records billions of dollars of sales in the United States annually, including many millions of dollars in annual revenue from sales in the Commonwealth of Virginia. Actavis sells its generic

prescription products primarily through "Watson Laboratories," which, on information and belief, refers to Watson Laboratories, Inc., and Actavis's affiliate "Watson Pharma," and markets these products to drug wholesalers, mail order, government and national retail drug and food store chains.

36. Watson makes and sells pharmaceutical products which it distributes in the Eastern District of Virginia and throughout the United States and for many years has had, and continues to have, substantial sales in this district.

37. In 2011, sales to Walgreen Co. and McKesson Corporation—both nationwide distributors having facilities in the Commonwealth of Virginia—accounted for 16% and 14%, respectively, of Actavis's (then Watson Pharmaceuticals, Inc.) net revenues.

38. Watson has maintained an active license with the Virginia Department of Health Professions as a "Non-Resident Wholesale Distributor" since at least 2004. On information and belief, pursuant to its Non-Resident Wholesale Distributor license, Watson distributes prescription drugs in Virginia.

39. In applying to become a "Non-Resident Wholesale Distributor," each applicant must designate a registered agent in Virginia for service of any notice or other legal document. Failure to designate an agent results in designation of the Secretary of the Commonwealth as the applicant's agent. For at least this reason, Watson has consented to service of process in the Commonwealth of Virginia.

40. Watson's affiliated distribution business, "Anda, Inc.," allows customers throughout the U.S. and in this judicial district to order products online "24/7" for next day delivery to the entire U.S. Anda, Inc. competes directly with Watson's large wholesale customers with respect to the distribution of generic products.

41. Watson Pharmaceuticals, Inc.'s 2011 10K additionally states that it is "the only U.S. pharmaceutical company that has meaningful distribution operations with direct access to independent pharmacies" and that its "distribution operation is a strategic asset in the national distribution of generic and brand pharmaceuticals." Its "Distribution business distributes products for over 360 suppliers and is focused on providing next-day delivery and responsive service to its customers" which are located throughout the United States. Its "Distribution business also distributes a number of Watson generic and brand products."

42. Watson solicits customers in Virginia using its extensive website. Watson, through its interactive website, allows customers throughout the U.S., including in this judicial district, to order Watson's generic products electronically by clicking on a hyperlink to andanet.com.

Apotex

43. Apotex Inc. is subject to personal jurisdiction in the Eastern District of Virginia because, among other things, Apotex Inc. directly and/or through its wholly owned affiliates for many years has had, and continues to, market and sell a substantial quantity of generic drugs throughout the United States, including within this district, and, therefore, purposefully avails itself of the privilege of conducting activities within this district.

44. Apotex Inc. solicits customers in Virginia through its extensive website. Through Apotex Inc.'s interactive website, customers and potential customers throughout the U.S., including in this judicial district, can, among other things: (a) submit online purchase inquiries; (b) download a catalogue of Apotex products ; and (c) access product return information.

45. Apotex Inc. has also previously availed itself of the benefits of this jurisdiction by filing suit in this Court. *See, e.g., Apotex, Inc. v. Novartis AG et al.*, 3:06-cv-698 (E.D. Va. 2006); *Apotex, Inc. v. Glaxo Group Ltd. et al.*, 2:07-cv-40 (E.D. Va. 2007).

46. Apotex Corp. is subject to personal jurisdiction in the Eastern District of Virginia due to, among other things, Apotex Corp.'s systematic, purposeful, and continuous contacts in this district.

47. On information and belief, Apotex Corp. is the exclusive licensed distributor and marketer of its parent company, Apotex, Inc., in the U.S. Apotex Corp. makes and sells pharmaceutical products which it distributes throughout the United States, including in the Eastern District of Virginia. Apotex Corp. and Apotex Inc. generate many millions of dollars in revenues from U.S. sales annually, including many millions of dollars in revenue from sales in the Commonwealth of Virginia.

48. Apotex Corp. has maintained an active license with the Virginia Department of Health Professions as a "Non-Resident Wholesale Distributor" since at least 2000. On information and belief, pursuant to its Non-Resident Wholesale Distributor license, Apotex Corp. distributes prescription drugs in Virginia.

49. In applying to become a "Non-Resident Wholesale Distributor," each applicant must designate a registered agent in Virginia for service of any notice or other legal document. Failure to designate an agent is deemed to have designated the Secretary of the Commonwealth as the applicant's agent. For at least this reason, Apotex Corp. has consented to service of process in the Commonwealth of Virginia.

50. Apotex Corp. is a pharmaceutical vendor for the MMCAP which sells pharmaceuticals in 46 states, including Virginia.

51. Apotex Inc. and Apotex Corp. solicit customers in Virginia using their extensive, linked websites. For example, through Apotex Corp.'s interactive website, customers and potential customers throughout the U.S., including in this judicial district, can, among other things: (a) submit online purchase inquiries; (b) download a catalogue of Apotex products ; and (c) access product return information.

BACKGROUND

The '048 Reissue Patent

52. On March 5, 2013, the United States Patent and Trademark Office ("USPTO") issued the '048 patent, titled "4-[5-(4-Methylphenyl)-3-(Trifluoromethyl)-1H-Pyrazol-1-YL]Benzenesulfonamide for the Treatment of Inflammation or an Inflammation-Associated Disorder." The United States Patent and Trademark Office reissued the '048 patent (reissue Application No. 12/205,319) from United States Patent No. 5,760,068 (the "'068 patent"), which originally issued on June 2, 1998.

53. The '048 patent discloses and claims, *inter alia*, "administering to the subject having or susceptible to arthritis, a therapeutically effective amount of" a compound known as celecoxib, "or a pharmaceutically-acceptable salt thereof." In addition to treating arthritis, the '048 patent has claims directed to treating pain, osteoarthritis, rheumatoid arthritis, juvenile arthritis, spondyloarthropathy and menstrual cramps.

Orange Book Listing for Celebrex®

54. G.D. Searle LLC holds an approved New Drug Application, No. 20-998, for celecoxib capsules, 50mg, 100mg, 200mg, and 400 mg dosage strengths, which it sells under the registered name Celebrex®. As stated in Pfizer's FDA approved label for Celebrex®, ("Pfizer's Celebrex® Label") the drug is indicated for the treatment of osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, and primary dysmenorrhea.

One or more claims of the '048 patent covers use of celecoxib to treat each of the indications in Pfizer's Celebrex® Label.

55. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, Pfizer is filing notice with the FDA to list the '048 patent in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the treatment of osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain and primary dysmenorrhea.

56. Pfizer's notice to list the '048 patent in the Orange Book states that the '048 patent's expiration date is June 2, 2015. The '048 patent has a pediatric exclusivity that expires December 2, 2015.

57. The Orange Book listing for Celebrex® also includes United States Patents Nos. 5,466,823 (the "'823 patent") and 5,563,165 (the "'165 patent"), and lists their expiration date as November 30, 2013. The Orange Book lists pediatric exclusivity for the '823 and '165 patents as expiring on May 30, 2014.

58. The Orange Book listing for Celebrex® also includes the '068 patent, and gives its expiration date as June 2, 2015. The Orange Book lists pediatric exclusivity for the '068 patent as expiring on December 2, 2015.

The Prior Teva Litigation

59. This is not the first time that a generic defendant has challenged Pfizer's patents protecting its Celebrex drug product. Teva previously filed ANDAs challenging the '823, '165, and '068 patents. Consequently, Pfizer sued Teva for infringement of those three patents, under 35 U.S.C. § 271(e)(2). The United States District Court for the District of New Jersey held that

the patents were valid, enforceable and infringed. *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 482 F. Supp. 2d 390 (D.N.J. 2007).

60. The United States Court of Appeals for the Federal Circuit affirmed validity, enforceability and infringement of the '823 and '165 patents and reversed the judgment of validity of the '068 patent, invalidating several claims for obviousness-type double patenting. *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008).

61. Following the Federal Circuit's ruling, Pfizer worked with the USPTO to correct prosecution errors, including the error that had led to the invalidation of the '068 patent.

62. On March 5, 2013, the USPTO issued the '048 patent as a valid reissue of the '068 patent.

DEFENDANTS' ANDAs

Lupin's ANDA

63. By letter dated December 30, 2010 ("Lupin's First Notice Letter"), Lupin notified Pfizer that it had filed ANDA No. 202240 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell 100 mg, 200 mg, and 400 mg celecoxib capsules, generic copies of Celebrex® (collectively with Lupin's 50 mg celecoxib capsules, "Lupin's ANDA Products") prior to the expiration of the '068 patent, and therefore prior to the expiration of the '048 patent.

64. Lupin's First Notice Letter stated that ANDA No. 202240 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that claims 1-17 of the '068 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's ANDA Products.

65. By letter dated July 27, 2011 ("Lupin's Second Notice Letter"), Lupin notified Pfizer that it had amended its ANDA to add 50 mg celecoxib capsules, and provided a

"Paragraph IV" certification that claims 1-17 of the '068 patent are invalid, unenforceable and/or not infringed.

66. On information and belief, Lupin intends, conditioned upon the FDA granting it tentative approval of ANDA number 202240, immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014, to market Lupin's ANDA Products for the treatment of disorders included in Pfizer's Celebrex® Label. Lupin also intends for doctors to prescribe, and for patients to use, Lupin's ANDA Products in accordance with and as directed by Lupin's proposed labeling for Lupin's ANDA Products, which copies some or all of the indications in Pfizer's Celebrex® Label.

Teva's ANDA

67. By letter dated January 6, 2004 ("Teva's First Notice Letter"), Teva notified Pfizer that it had filed ANDA No. 76-898 with the FDA, seeking approval under the FDCA to market and sell 100 mg, 200 mg, and 400 mg celecoxib capsules, generic copies of Celebrex® (collectively with Teva's 50 mg celecoxib capsules, "Teva's ANDA Products"), prior to the expiration of the '823, '165, and '068 patent, and therefore prior to the expiration of the '048 patent.

68. Teva's First Notice Letter stated that ANDA No. 76-898 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the '823, '165, and '068 patents are invalid, unenforceable or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Products.

69. By letter dated April 3, 2008 ("Teva's Second Notice Letter"), Teva notified Pfizer that it had amended its ANDA to add 50 mg celecoxib capsules, and provided a "Paragraph IV" certification that the '068 patent was invalid, unenforceable or not infringed.

70. On information and belief, the FDA granted tentative approval of ANDA No. 76-898 on April 27, 2012.

71. On information and belief, Teva intends, immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014, to market Teva's ANDA Products for treatment of disorders included in Pfizer's Celebrex® Label and Teva intends for doctors to prescribe, and patients to use, Teva's ANDA Products in accordance with and as directed by Teva's proposed labeling for Teva's ANDA Products which copies some or all of the indications in Pfizer's Celebrex® Label.

Mylan's ANDA

72. By letter dated March 20, 2008 ("Mylan's First Notice Letter"), Mylan notified Pfizer that it had filed ANDA No. 78-857 with the FDA, seeking approval under the FDCA to market and sell 50 mg, 100 mg, 200 mg, and 400 mg celecoxib capsules, generic copies of Celebrex® (collectively, "Mylan's ANDA Products"), prior to the expiration of the '068 patent, and therefore prior to the expiration of the '048 patent.

73. Mylan's First Notice Letter stated that, for its ANDA No. 78-857, it was amending its original "Paragraph III" certification on the '068 patent to a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to allege that the '068 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products.

74. By letter dated March 25, 2011 ("Mylan's Second Notice Letter"), Mylan notified Pfizer that it was "remak[ing] a Paragraph IV certification" that the '068 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products.

75. On information and belief, the FDA granted tentative approval of ANDA No. 78-857 on April 29, 2011.

76. On information and belief, Mylan intends, immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014, to market Mylan's ANDA Products for the treatment of disorders included in Pfizer's Celebrex® Label, and Mylan intends for doctors to prescribe, and patients to use, Mylan's ANDA Products in accordance with and as directed by Mylan's proposed labeling for Mylan's ANDA Products which copies some or all of the indications in Pfizer's Celebrex® Label.

Watson's ANDA

77. By letter dated February 1, 2010 ("Watson's First Notice Letter"), Watson notified Pfizer that it had filed ANDA No. 200562 with the FDA, seeking approval under the FDCA to market and sell 100 mg, 200 mg, and 400 mg celecoxib capsules, generic copies of Celebrex® (collectively with Watson's 50 mg celecoxib capsules, "Watson's ANDA Products") prior to the expiration of the '068 patent, and therefore prior to the expiration of the '048 patent.

78. Watson's First Notice Letter stated that ANDA No. 200562 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the '068 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Watson's ANDA Products.

79. By letter dated November 12, 2010 ("Watson's Second Notice Letter"), Watson notified Pfizer that it had amended its ANDA to add 50 mg celecoxib capsules, and provided a "Paragraph IV" certification that the '068 patent is invalid, unenforceable and/or not infringed.

80. On information and belief, the FDA granted tentative approval of ANDA No. 200562, on September 21, 2012.

81. On information and belief, Watson intends, immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014, to market Watson's ANDA Products for the treatment of disorders included in Pfizer's Celebrex® Label, and Watson intends for doctors to prescribe, and patients to use, Watson's ANDA Products in accordance with and as directed by Watson's proposed labeling for Watson's ANDA Products which copies some or all of the indications in Pfizer's Celebrex® Label.

Apotex Inc. and Apotex Corp.'s ANDA

82. By letter dated July 17, 2012 ("Apotex's Notice Letter"), Apotex Inc., through its agent Apotex Corp. (collectively, "Apotex"), notified Pfizer that it had filed ANDA No. 204197 with the FDA, seeking approval under the FDCA to market and sell 50 mg, 100 mg, and 200 mg celecoxib capsules, generic copies of Celebrex® (Apotex's ANDA Products) prior to the expiration of the '068 patent, and therefore prior to the expiration of the '048 patent.

83. Apotex's Notice Letter stated that ANDA No. 204197 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '068 patent are invalid, or otherwise unenforceable, and/or will not be infringed, by the commercial manufacture, use, or sale of Apotex's ANDA Products.

84. On information and belief, Apotex Inc. and Apotex Corp. intend, conditioned upon the FDA granting them tentative approval of ANDA No. 204197, immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014, to market Apotex's ANDA Products for the treatment of disorders included in Pfizer's Celebrex® Label, and they intend for doctors to prescribe, and patients to use, Apotex's ANDA Products in accordance with and as directed by Apotex's proposed labeling for Apotex's ANDA Products which copies some or all of the indications in Pfizer's Celebrex® Label.

IRREPARABLE HARM

85. At stake in the present litigation is the roughly 18 months of patent exclusivity between the expiration (on May 30, 2014) of the exclusivity associated with the '823 and '165 patents and the expiration (on December 2, 2015) of the exclusivity associated with the '048 patent. Court orders upholding the validity, enforceability and infringement of the '823 and '165 patents prevent Defendants from obtaining approval and launching their generic Celebrex products prior to the expiration of the exclusivity associated with those patents. However, absent a similar Court order with respect to the '048 patent, Pfizer believes that one or more generic Defendants will attempt to launch generic Celebrex "at risk" on or about May 30, 2014, more than 18 months before the expiration of the exclusivity associated with the '048 patent.

86. If any defendant is permitted to market its ANDA Product ("ANDA Product" refers to any one of Lupin, Teva, Mylan, Watson, or Apotex's ANDA Products) prior to the expiration of the '048 patent, and the associated pediatric exclusivity, Pfizer will suffer irreparable harm because such sales will likely result in irreversible price erosion of the mean price for the celecoxib molecule, reduced patient access to the Celebrex® brand, loss of good will associated with the Celebrex® brand, and notable organizational change.

COUNT I : Lupin's ANDA Filing Infringes the '048 Patent
(Patent Infringement)

87. The allegations of paragraphs 1 through 86 above are repeated and re-alleged as if set forth fully herein.

88. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin's filing of ANDA No. 202240 seeking approval to market Lupin's ANDA Products prior to expiration of the '048 patent is an act of infringement of one or more claims of the '048 patent, and entitles Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective

date of approval for ANDA No. 202240 be a date which is not earlier than the expiration date of the '048 patent, including any exclusivity to which Pfizer is or becomes entitled.

89. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 202240 states that Lupin's ANDA Products are indicated for the treatment of one or more disorders included in Pfizer's Celebrex® Label.

90. Upon information and belief, Lupin, conditioned upon the FDA granting it tentative approval of ANDA number 202240, intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014. The use of Lupin's ANDA Products in accordance with and as directed by Lupin's proposed labeling would infringe one or more claims of the '048 patent.

91. Upon information and belief, Lupin intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

92. Upon information and belief, Lupin knows that Lupin's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '048 patent and that Lupin's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

93. Upon information and belief, Lupin intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

94. The foregoing actions by Lupin constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more claims

of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

95. Pfizer will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

COUNT II : Teva's ANDA Filing Infringes the '048 Patent
(Patent Infringement)

96. The allegations of paragraphs 1 through 95 above are repeated and re-alleged as if set forth fully herein.

97. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva's filing of ANDA No. 76-898 seeking approval to market Teva's ANDA Products prior to expiration of the '048 patent is an act of infringement of one or more claims of the '048 patent, and entitles Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 76-898 be a date which is not earlier than the expiration date of the '048 patent, including any exclusivity to which Pfizer is or becomes entitled.

98. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 76-898 states that Teva's ANDA Products are indicated for the treatment of one or more disorders covered by Pfizer's Celebrex® Label.

99. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014. The use of Teva's ANDA Products in accordance with and as directed by Teva's proposed labeling would infringe one or more claims of the '048 patent.

100. Upon information and belief, Teva intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

101. Upon information and belief, Teva knows that Teva's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '048 patent and that Teva's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

102. Upon information and belief, Teva intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents on, May 30, 2014.

103. The foregoing actions by Teva constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more claims of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

104. Pfizer will be substantially and irreparably harmed if Teva is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

COUNT III : Mylan's ANDA Filing Infringes the '048 Patent
(Patent Infringement)

105. The allegations of paragraphs 1 through 104 above are repeated and re-alleged as if set forth fully herein.

106. Pursuant to 35 U.S.C. § 271(e)(2)(A), Mylan's filing of ANDA No. 78-857 seeking approval to market Mylan's ANDA Products prior to expiration of the '048 patent is an act of infringement of one or more claims of the '048 patent, and entitles Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective

date of approval for ANDA No. 78-857 be a date which is not earlier than the expiration date of the '048 patent, including any exclusivity to which Pfizer is or becomes entitled.

107. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 78-857 states that Mylan's ANDA Products are indicated for the treatment of one or more disorders covered by Pfizer's label for Celebrex®.

108. Upon information and belief, Mylan intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014. The use of Mylan's ANDA Products in accordance with and as directed by Mylan's proposed labeling would infringe one or more claims of the '048 patent.

109. Upon information and belief, Mylan intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period of the '823 and '165 patents, on May 30, 2014.

110. Upon information and belief, Mylan knows that Mylan's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '048 patent and that Mylan's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

111. Upon information and belief, Mylan intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

112. The foregoing actions by Mylan constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more

claims of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

113. Pfizer will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

COUNT IV : Watson's ANDA Filing Infringes the '048 Patent
(Patent Infringement)

114. The allegations of paragraphs 1 through 113 above are repeated and re-alleged as if set forth fully herein.

115. Pursuant to 35 U.S.C. § 271(e)(2)(A), Watson's filing of ANDA No. 200562 seeking approval to market Watson's ANDA Products prior to expiration of the '048 patent is an act of infringement of one or more claims of the '048 patent, and entitles Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 200562 be a date which is not earlier than the expiration date of the '048 patent, including any exclusivity to which Pfizer is or becomes entitled.

116. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 200562 states that Watson's ANDA Products are indicated for the treatment of one or more disorders covered by Pfizer's label for Celebrex®.

117. Upon information and belief, Watson intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Watson's ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014. The use of Watson's ANDA Products in accordance with and as directed by Watson's proposed labeling would infringe one or more claims of the '048 patent.

118. Upon information and belief, Watson intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

119. Upon information and belief, Watson knows that Watson's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '048 patent and that Watson's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

120. Upon information and belief, Watson intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

121. The foregoing actions by Watson constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more claims of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

122. Pfizer will be substantially and irreparably harmed if Watson is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

COUNT V : Apotex's ANDA Filing Infringes the '048 Patent
(Patent Infringement)

123. The allegations of paragraphs 1 through 122 above are repeated and re-alleged as if set forth fully herein.

124. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex's filing of ANDA No. 204197 seeking approval to market Apotex's ANDA Products prior to expiration of the '048 patent is an act of infringement of one or more claims of the '048 patent, and entitles Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective

date of approval for ANDA No. 204197 be a date which is not earlier than the expiration date of the '048 patent, including any exclusivity to which Pfizer is or becomes entitled.

125. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 204197 states that Apotex's ANDA Products are indicated for the treatment of one or more disorders covered by Pfizer's label for Celebrex®.

126. Upon information and belief, conditioned upon the FDA granting them tentative approval of ANDA No. 204197, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014. The use of Apotex's ANDA Products in accordance with and as directed by Apotex's proposed labeling would infringe one or more claims of the '048 patent.

127. Upon information and belief, Apotex intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

128. Upon information and belief, Apotex knows that Apotex's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '048 patent and that Apotex's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

129. Upon information and belief, Apotex intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

130. The foregoing actions by Apotex constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more

claims of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

131. Pfizer will be substantially and irreparably harmed if Apotex is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

COUNT VI : Declaratory Judgment that Lupin Will Infringe the '048 Patent
(Declaratory Judgment of Infringement)

132. Pfizer repeats and re-alleges paragraphs 1 through 131 above as if fully set forth herein.

133. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

134. Upon information and belief, Lupin has taken active steps relating to importing, using, selling, or offering for sale in the United States, including in the Eastern District of Virginia, the Lupin ANDA Products with the proposed labeling immediately following FDA approval of ANDA No. 202240. Lupin's active steps include, among other things, filing ANDA No. 202240 and challenging the validity of the '068 patent by its Paragraph IV certification and Notice Letter to Pfizer. As a result, Lupin is committed to selling Lupin's ANDA Products immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents on May 30, 2014.

135. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 202240 states that Lupin's ANDA Products are indicated for the treatment of one or more indications included in the Pfizer's Celebrex® Label.

136. Upon information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on

May 30, 2014. The use of Lupin's ANDA Products in accordance with and as directed by Lupin's proposed labeling would infringe one or more claims of the '048 patent.

137. Upon information and belief, Lupin intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

138. Upon information and belief, Lupin knows that Lupin's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '048 patent and that Lupin's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

139. Upon information and belief, Lupin intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

140. The foregoing actions by Lupin constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more claims of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

141. Pfizer will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

COUNT VII : Declaratory Judgment that Teva Will Infringe the '048 Patent
(Declaratory Judgment That ANDA Products Will Infringe)

142. Pfizer repeats and re-alleges paragraphs 1 through 141 above as if fully set forth herein.

143. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

144. Upon information and belief, Teva has taken active steps relating to importing, using, selling, or offering for sale in the United States, including in the Eastern District of Virginia, the Teva ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014. Teva's active steps include, among other things, filing ANDA No. 76-898, challenging the validity of the '068 patent by its Paragraph IV certification and Notice Letter(s) to Pfizer, and obtaining tentative approval with respect to ANDA No. 76-898. As a result, Teva is committed to selling Teva's ANDA Products immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

145. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 76-898 states that Teva's ANDA Products are indicated for the treatment of one or more indications included in Pfizer's Celebrex® Label.

146. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity for the '823 and '165 patents, on May 30, 2014. The use of Teva's ANDA Products in accordance with and as directed by Teva's proposed labeling would infringe one or more claims of the '048 patent.

147. Upon information and belief, Teva intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

148. Upon information and belief, Teva knows that Teva's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the

'048 patent and that Teva's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

149. Upon information and belief, Teva intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

150. The foregoing actions by Teva constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more claims of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

151. Pfizer will be substantially and irreparably harmed if Teva is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

COUNT VIII : Declaratory Judgment that Mylan Will Infringe the '048 Patent
(Declaratory Judgment That ANDA Products Will Infringe)

152. Pfizer repeats and re-alleges paragraphs 1 through 151 above as if fully set forth herein.

153. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

154. Upon information and belief, Mylan has taken active steps relating to importing, using, selling, or offering for sale in the United States, including in the Eastern District of Virginia, the Mylan ANDA Products with the proposed labeling immediately following FDA approval of ANDA No. 78-857. Mylan's active steps include, among other things, filing ANDA No. 78-857, challenging the validity of the '068 patent by its Paragraph IV certification and Notice Letter to Pfizer, and obtaining tentative approval with respect to ANDA No. 78-857. As

a result, Mylan is committed to selling Mylan ANDA Products immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

155. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 78-857 states that Mylan's ANDA Products are indicated for the treatment of one or more indications included in Pfizer's Celebrex® Label.

156. Upon information and belief, Mylan intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165, patents on May 30, 2014. The use of Mylan's ANDA Products in accordance with and as directed by Mylan's proposed labeling would infringe one or more claims of the '048 patent.

157. Upon information and belief, Mylan intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

158. Upon information and belief, Mylan knows that Mylan's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '048 patent and that Mylan's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

159. Upon information and belief, Mylan intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

160. The foregoing actions by Mylan constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more

claims of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

161. Pfizer will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

COUNT IX : Declaratory Judgment that Watson Will Infringe the '048 Patent (Declaratory Judgment That ANDA Products Will Infringe)

162. Pfizer repeats and re-alleges paragraphs 1 through 161 above as if fully set forth herein.

163. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

164. Upon information and belief, Watson has taken active steps relating to importing, using, selling, or offering for sale in the United States, including in the Eastern District of Virginia, the Watson ANDA Products with the proposed labeling immediately following FDA approval of ANDA No. 200562. Watson's active steps include, among other things, filing ANDA No. 200562, challenging the validity of the '068 patent by its Paragraph IV certification and Notice Letter to Pfizer, and obtaining tentative approval with respect to ANDA No. 200562. As a result, Watson is committed to selling Watson's ANDA Products immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

165. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 200562 states that Watson's ANDA Products are indicated for the treatment of one or more indications in Pfizer's Celebrex® Label.

166. Upon information and belief, Watson intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Watson's ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on

May 30, 2014. The use of Watson's ANDA Products in accordance with and as directed by Watson's proposed labeling would infringe one or more claims of the '048 patent.

167. Upon information and belief, Watson intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

168. Upon information and belief, Watson knows that Watson's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '048 patent and that Watson's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

169. Upon information and belief, Watson intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents on, May 30, 2014.

170. The foregoing actions by Watson constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more claims of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

171. Pfizer will be substantially and irreparably harmed if Watson is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

COUNT X : Declaratory Judgment that Apotex Will Infringe the '048 Patent
(Declaratory Judgment That ANDA Products Will Infringe)

172. Pfizer repeats and re-alleges paragraphs 1 through 171 above as if fully set forth herein.

173. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

174. Upon information and belief, Apotex has taken active steps relating to importing, using, selling, or offering for sale in the United States, including in the Eastern District of Virginia, the Apotex ANDA Products with the proposed labeling immediately following FDA approval of ANDA No. 204197. Apotex's active steps include, among other things, filing ANDA No. 204197 and challenging the validity of the '068 patent by its Paragraph IV certification and Notice Letter to Pfizer. As a result, Apotex is committed to selling Apotex's ANDA Products immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

175. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 204197 states that Apotex's ANDA Products are indicated for the treatment of one or more indications included in Pfizer's Celebrex® Label.

176. Upon information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Products with the proposed labeling immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014. The use of Apotex's ANDA Products in accordance with and as directed by Apotex's proposed labeling would infringe one or more claims of the '048 patent.

177. Upon information and belief, Apotex intends to actively induce infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

178. Upon information and belief, Apotex knows Apotex's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '048 patent and that Apotex's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

179. Upon information and belief, Apotex intends to contribute to the infringement of one or more claims of the '048 patent immediately upon expiration of the pediatric exclusivity period for the '823 and '165 patents, on May 30, 2014.

180. The foregoing actions by Apotex constitute and/or would constitute infringement of one or more claims of the '048 patent, active inducement of infringement of one or more claims of the '048 patent, and/or contribution to the infringement by others of one or more claims of the '048 patent.

181. Pfizer will be substantially and irreparably harmed if Apotex is not enjoined from infringing the '048 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment declaring that each Defendant's submission and maintenance of its respective ANDA was an act of infringement and that each Defendant's making, using, offering to sell, selling, or importing its respective ANDA Products prior to the expiration of the '048 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '048 patent and that this patent remains valid and enforceable;

B. A judgment declaring that the effective date of any approval for each Defendant to make, use, offer for sale, sell, market, distribute, or import its ANDA Products be no earlier than the expiration of the '048 patent;

C. A permanent injunction against each Defendant, its respective officers, agents, servants, and employees, and those persons in active concert or

participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing their ANDA Products, or any other infringement of the '048 patent, and enjoining each Defendant from inducing or contributing to any of the foregoing, prior to the expiration of the '048 patent;

D. A declaratory judgment that each Defendant's making, using, offering to sell, selling, or importing its respective ANDA Products prior to the expiration of the '048 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '048 patent;

E. If any Defendant commercially manufactures, uses, offers to sell or sells its ANDA Product within the United States, or imports into the United States, prior to the expiration of the '048 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

F. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

G. An award of Plaintiffs' costs and expenses in this action; and

H. Such further and additional relief as this Court deems just and proper.

Dated: March 5, 2013

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